

REMARKS

Claims 1-22, 27, 31, and 32, which were withdrawn as drawn to a non-elected invention, have been cancelled. Claims 23-26 and 28-30 are pending. Claims 31 and 32 are new. Support for these claims can be found on page 9, line 20 of the Applicants' specification.

Claim 23 is objected to because of a typographical error. Claim 23 has been amended to correct the error. Withdrawal of the rejection is respectfully requested.

Claims 23-26 and 28-30 stand rejected under 35 U.S.C. § 112 as being indefinite. Specifically, the rejection states that the structure of Formula II in Claim 23 should be presented with a positive charge. Claim 23 is also rejected for lacking proper antecedent basis for "said amount." Claim 23 has been amended to correct the error. Withdrawal of the rejection is respectfully requested.

Claims 23-26 and 28-30 are rejected under 35 U.S.C. § 103(a) as being obvious over Angelo which teaches detection of EDDP in urine samples. The rejection states that it would be obvious to one of skill in the art to prepare a pharmaceutical composition with EDDP with pharmaceutically acceptable agents in view of Angelo.

Angelo teaches an enantioselective assay for detecting and distinguishing methadone and the primary metabolite of methadone, EDDP. However, Angelo is silent as to any potential biological activities of EDDP. In light of Angelo's failure to recognize any activity of EDDP, the Applicants respectfully submit that one skilled in the art would have no motivation or reasonable expectation of success of providing analgesia or drug deterrence in a pharmaceutical composition containing a metabolite found in urine.

Methadone is believed to induce analgesia through interaction with NMDA and aid in drug deterrence therapy by acting on opioid receptors. However, the ability of methadone or its

metabolites to affect the nAChR was not recognized by Angelo. Therefore, if one skilled in the art were to hypothetically assume that EDDP possessed biological activity, he or she would expect it to function through the same pathway as the parent molecule - by blocking opioid or NMDA receptors, but not nAChR receptors.

The Applicants' experiments unexpectedly discovered that EDDP has different physiological functions than d-methadone, an opioid blocker, and MK-801, an NMDA blocker. For example, the specification shows that only 10 μ M of methadone or MK-801 are required to block catecholamine release, whereas 100 μ M of EDDP is required to have an effect (See, Figs. 13 and 14 and Page 4, lines 20-32 of the Applicants' specification). In contrast, EDDP affects nicotinic acetylcholine receptors with five times the potency of methadone. The different inhibitory concentrations of these compounds for different receptor molecules indicates that EDDP has a distinct and unexpected biological function from the parent molecule. Therefore, the Applicants respectfully submit that one skilled in the art in view of Angelo could not have predicted a composition comprising EDDP would act on nicotinic receptors to induce analgesia and deter drug abuse.

In light of Angelo's failure to recognize the biological activity of EDDP and the distinctly different biological activity of EDDP and its parent molecule, the Applicants respectfully submit that a pharmaceutical composition comprising EDDP having analgesic and drug deterrence activity by way of a nicotinic receptor is non-obvious. Furthermore, since one skilled in the art would not have been motivated to make a pharmaceutical composition comprising EDDP, the amount sufficient to induce analgesia or deter abuse of abusive substances is also non-obvious. Accordingly, the Applicants respectfully submit that the subject matter of Claims 23-26 and 28-

30 is non-obvious and respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. § 103(a).

In light of the foregoing, the Applicants respectfully submit that the entire Application is now in condition for allowance, which is respectfully requested.

Respectfully submitted,



T. Daniel Christenbury
Reg. No. 31,750
Attorney for Applicants

TDC/LL/rb
(215) 656-3381